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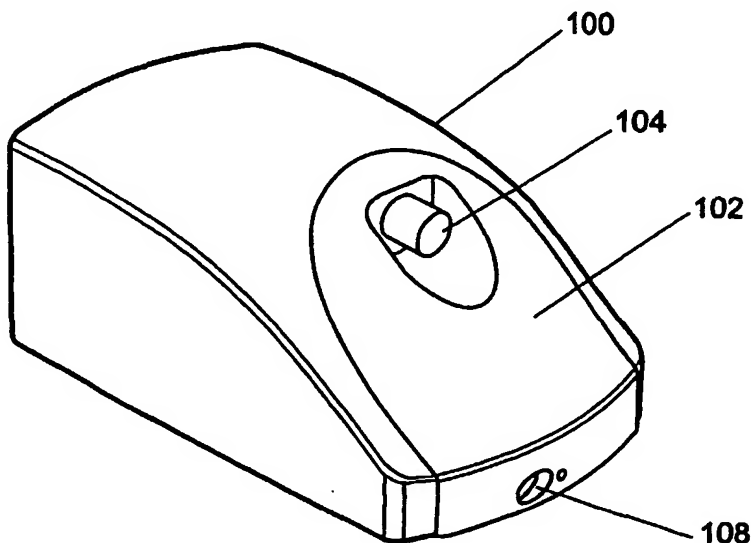
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(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: The present invention may include an integral, separable or separate humidifier (100) which may be selectively configured to an inoperative or operative state. The switch over is dependent on the user or the seller having access to an actuation tool to activate the humidifier. The Continuous Positive Airway Pressure (CPAP) device is initially available for use as a standalone CPAP (100). The heater plate being isolated by a covering shroud (102), the shroud (102) also forms a connection port for the CPAP blower outlet (104). The heated humidification hardware being disabled by the absence of the activation tool. Upgrade to a CPAP device including heated humidification is completed by the installation of the actuation tool. Removal of the heater plate

isolating shroud and/or installing the actuation tool enables the software controlled heated humidification hardware for heated humidifier operation. Other upgrades to functionality are also disclosed.

“BREATHING ASSISTANCE APPARATUS”**FIELD OF INVENTION**

The present invention relates to humidification particularly though not solely to humidifying gases to a user requiring Continuous Positive Airway Pressure (CPAP).

SUMMARY OF THE PRIOR ART

It is known in the art to provide CPAP treatment in conjunction with humidity, see for example United States Patent Number 6,050,260. The humidification is usually provided either by:

1. An integrated CPAP blower and humidifier as described in US 6,050,260, whereby there is no separation of the CPAP and heated humidifier except for the humidification chamber for filling and cleaning.
2. A standalone CPAP device connected by a flexible airway tube to a standalone heated humidifier, the equipment generally mounted on a tray for stability.
3. A CPAP device that can standalone but can also be attached to a modular heated humidifier. No flexible airway tube nor mounting tray is required.

It would be desirable to provide a CPAP device which could be easily upgraded to provide humidification.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a breathing assistance apparatus which goes some way to achieving the abovementioned desiderata, overcoming the abovementioned disadvantages or at least provides the public with a useful choice.

Accordingly in a first aspect the invention consists in a breathing assistance apparatus comprising:

a gas delivery device adapted to provide gas at a substantially positive mean pressure;

a humidifier adapted to humidify said gas and;

wherein said apparatus is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device operable and a second configuration with said predetermined functionality and said device operable.

In a second aspect the invention consists in a breathing assistance apparatus comprising:

means for providing gas at a substantially positive mean pressure;

means for humidifying said gas; and

means for providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

In a third aspect the invention consists in a method of delivering respiratory gases to a patient comprising the steps of:

providing gas at a substantially positive mean pressure;

humidifying said gas; and

providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

Wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus.

Wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus said second configuration occurs by the engagement of a predetermined magnetic key with said apparatus.

Wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with

said apparatus said second configuration occurs by the entry of a predetermined code into a keypad.

Wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with
5 said apparatus a portion of said apparatus may be separated corresponding to said first configuration, whereby the integration of said portion corresponds to said second configuration.

Wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with
10 said apparatus said second configuration occurs by introducing a software or hardware dongle.

Wherein said apparatus further comprises a conduit between the device and the patient and said predetermined functionality is active humidification and heater within or incorporated with said conduit.

15 Wherein said predetermined functionality relates to heating said gas and said second configuration relates to energising said heater to heat said conduit and/or said gas directly.

Wherein said predetermined functionality relates to storage or display of data relating to the use of said apparatus and said second configuration relates to energising a
20 display to indicate said use.

Wherein said predetermined functionality relates to the pressure level, delivered to the patient and said second configuration relates to providing either a continuous or stepwise correction in sound pressure level.

In a fourth aspect the invention consists in a apparatus for delivering gas to a
25 patient comprising a gas delivery device configured to provide gas at a predetermined pressure level,

a heater,

a chamber having an inlet and an outlet,

said inlet configured to receive gas from said device,

including a body of water whereby said body of water being heated by said heater providing vapour within said chamber thereby humidifying gases passing from said inlet to said outlet,

5 a controller or processor configured to energise said heater according to at least a user selectable level,

a cover configured to prevent user selection of said heating level and providing an outlet directly from said device,

10 wherein when said chamber is installed in proximity to said heater said apparatus delivers humidified gas to a patient at a predetermined pressure level,

and when said chamber is removed and said cover is installed said apparatus delivers unhumidified gas to a patient at a predetermined pressure level.

Wherein said cover may be removed using a mechanical key to disengage it with said apparatus.

15 Wherein said apparatus further comprises a control input configured to provide user selection to said controller.

Wherein said input may be locked to prevent user input and unlocked by engaging a mechanical key with said input.

20 In a fifth aspect the invention consists in a apparatus for delivering gas to a patient comprising a gas delivery device configured to provide gas at a predetermined pressure level,

a heater,

a chamber having an inlet and an outlet,

said inlet configured to receive gas from said device,

25 including a body of water whereby said body of water being heated by said heater providing vapour within said chamber thereby humidifying gases passing from said inlet to said outlet,

a controller or processor configured to energise said heater according to at least a user selectable level.

a user input configured to selectively enable or disable said heater and/or other functionality associated with said apparatus.

5 Wherein said apparatus further comprises a display adapted to indicate the current level of functionality enabled.

10 This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

15 **BRIEF DESCRIPTION OF THE DRAWINGS**

One preferred form of the present invention will now be described with reference to the accompanying drawings in which

Figure 1 is a perspective view of the CPAP only configuration;

Figure 2A is a blown out view of the CPAP only configuration;

20 Figure 2B is a reverse angle of figure 2A;

Figure 3 is a perspective view of the humidified CPAP configuration;

Figure 4 is a front view showing another example control panel; and

Figure 5 is a front view showing an alternative control panel.

DETAILED DESCRIPTION

25 A typical integrated CPAP humidifier is described in United States Patent No. 6,050,260. The contents of which are incorporated herein by reference.

The present invention may include an integral, separable or separate humidifier which may be selectively configured to an inoperative or operative state. The switch over is dependent on the user or the seller having access to an actuation tool (described later) to activate the humidifier.

5 Referring to Figure 1 the CPAP device 100 is initially available for use as a standalone CPAP. The heater plate being isolated by a covering shroud 102, the shroud also forms a connection port for the CPAP blower outlet 104. The heated humidification hardware being disabled by the absence of the activation tool.

10 Upgrade to a CPAP device including heated humidification is completed by the installation of the actuation tool. Removal of the heater plate isolating shroud 102 shown in Figure 3, and/or installing the actuation tool enables the software controlled heated humidification hardware 106 for heated humidifier operation.

Examples of the various forms of actuation tool could include:

1. Software key via serial data port

15 The CPAP device could be connected via RS232 serial connection to a computer or directly via TCP/IP or telephone line to the Internet to receive either additional software or coded actuation data.

2. Mechanical Key

20 The heater plate vestibule is covered by a shroud. A mechanical key (110, Figure 2A) is used to remove the shroud. The heater plate control knob 108 is locked off by the shroud 102 as shown in Figure 2A. The upgrade kit may include a knob to turn the heater plate on. In one embodiment shown in Figures 2A & 2B engaging the key 110 pushes two snap fit flanges 112, allowing the shroud 102 to be removed.

3. Magnetic Key

25 Also includes a shroud as in Figure 2 but in addition there is a key which has magnets in a predetermined pattern. This key is slid into a cavity in the case. Inside the case there are Hall effect sensors that detect the pattern of magnets. If the key is detected, the heater plate is activated.

4. Code Number Verification

Also includes a shroud as in Figure 2 but in addition there is a code number that is entered into the device. The dealer phones a freephone number with the serial number of the CPAP device and pays for the upgrade. The freephone service then gives the dealer a code number that is specific to the serial number of the CPAP device. This code number is then entered into a keypad (not shown) to activate the humidifier.

The freephone service could also be an Internet based service.

Another alternative is that the upgrade kit includes a card with a number hidden inside the packaging. This number then gives the freephone service evidence that the dealer has paid for the kit, and the financial transaction then doesn't have to be conducted on the phone. Similarly to prevent fraud the numbers could be stored such that if a number is used twice an alarm is raised.

5. Dongle

A plug in pack containing an electronic circuit designed to respond in a predetermined way to interrogation by the CPAP device. The plug in pack could plug into a dedicated socket in the device or into the existing serial port. Similarly a smart card of known type could be interfaced with the CPAP device to activate the humidifier.

Additionally, the dongle may contain some of the electronic circuit needed to operate the heater plate. Again a shroud as seen in Figures 1 and 2 would be required.

6. Removable Heater Plate

The CPAP device is supplied with a plastic cradle where the heater plate currently is. The plastic cradle has all of the mounting and springing arrangement that the current heater plate has. the cradle also has an electrical connector and clips. A second part consisting of the pressed metal heater plate top surface with the element, thermistor and thermal cutout bonded to it is then supplied in the upgrade kit. The dealer can then remove the shroud and plug the heater plate into the cradle. The plastic cradle means that the fixings and spring mechanism can be preassembled inside the unit so that the heater plate can be installed without tools and without the need to disassemble the unit.

It will be appreciated that while in the preferred embodiment the unhumidified CPAP configuration utilises a shroud over the heater plate, this is not required. The heater plate, could be rendered in operable/by operable any of the methods described, but with the water chamber in place in both configuration.

5 7. Cold passover

Whereas the system in Figure 3 includes at least the water chamber this could operate in both humidified and non humidified modes. For example the heater plate need not be initially supplied. The heater plate may be supplied but not activated.

Activating the heater plate could occur for example:

- 10 1. Heater plate control is by a rotary potentiometer 108. This can be incapacitated by a lock to physically prevent the potentiometer from turning. Upgrade to active humidification requires a second key to remove the potentiometer lock and activate the heater.
 - 15 2. Heater control is by a setting in a menu accessed by buttons. Upgrade to active humidification requires a PIN number to activate the heater plate.
- Referring to Figure 5 the key pad 500 is shown.

8. Heated Tube

The system could include a heated tube to deliver the gas to avoid condensation. Again this might be incapacitated initially.

20 Activating the heated tube control could occur by example:

1. Heater tube control by a rotary potentiometer, which is locked to physically prevent the potentiometer from turning. Upgrade requires a third key to remove the heated tube potentiometer lock and activate the heated tube.
- 25 2. Heated tube control by a setting in a menu accessed by buttons. Upgrade requires a PIN number to activate the heated tube.

Example upgrade kits could be:

Cold passover kit: Contains a chamber, key #1 to remove cover.

Heated humidification kit: Contains chamber, key #1 to remove cover and key #2 to remove the potentiometer lock OR a PIN number to activate the heater.

Heated tube kit: Contains chamber, key #1 to remove cover, key #2 to remove the potentiometer lock OR a PIN number to activate the heater. Key #3 to remove the heated tube potentiometer lock OR a second PIN number.

9. Other Functionality Upgrade

The electronic or mechanical key could also be used to upgrade other functionality. For example the applicant has identified it might be desirable to store and/or display data in relation to patient compliance, or use of the treatment.

Referring to Figure 5 we see a screen 502 for display of such compliance data. Depending on the key used example levels of functionality are given below:

Option 1: Machine displays no information.

Option 2: Machine displays machine run time only.

Option 3: Machine displays summary data on the display. For example, average hours complied per night used.

Option 4: Full compliance data download. All the day to data stored in the machine can be downloaded to a PC for analysis. Summary data would also be displayed.

It would be possible to activate any of these options by entering a suitable PIN number, or any other method, previously described or not.

This method could also apply to upgrading any function of the machine for example different levels of delivered pressure for inhalation versus exhalation and automatically calibrating the pressure level depending on symptoms exhibited by the patient.

CLAIMS:

1 A breathing assistance apparatus comprising:

a gas delivery device adapted to provide gas at a substantially positive mean pressure;

5 a humidifier adapted to humidify said gas and;

wherein said apparatus is configurable to at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device operable and a second configuration with said predetermined functionality and said device operable.

10 2. A breathing assistance apparatus comprising:

means for providing gas at a substantially positive mean pressure;

means for humidifying said gas; and

15 means for providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

3. A method of delivering respiratory gases to a patient comprising the steps of:

providing gas at a substantially positive mean pressure;

humidifying said gas; and

20 providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

4. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus.

25 5. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus said

second configuration occurs by the engagement of a predetermined magnetic key with said apparatus.

6. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus said second configuration occurs by the entry of a predetermined code into a keypad.

7. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus a portion of said apparatus may be separated corresponding to said first configuration, whereby the integration of said portion corresponds to said second configuration.

8. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality is active humidification and said second configuration occurs by the engagement of a predetermined mechanical key with said apparatus said second configuration occurs by introducing a software or hardware dongle.

9. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said apparatus further comprises a conduit between the device and the patient and said predetermined functionality is active humidification and heater within or incorporated with said conduit.

10. An apparatus or method as claimed in claim 9 wherein said predetermined functionality relates to heating said gas and said second configuration relates to energising said heater to heat said conduit and/or said gas directly.

11. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality relates to storage or display of data relating to the use of said apparatus and said second configuration relates to energising a display to indicate said use.

12. An apparatus or method as claimed in anyone of claims 1 to 3 wherein said predetermined functionality relates to the pressure level, delivered to the patient and said

second configuration relates to providing either a continuous or stepwise correction in sound pressure level.

13. An apparatus for delivering gas to a patient comprising a gas delivery device configured to provide gas at a predetermined pressure level,

5 a heater,

a chamber having an inlet and an outlet,

said inlet configured to receive gas from said device,

including a body of water whereby said body of water being heated by said heater providing vapour within said chamber thereby humidifying gases passing from said inlet
10 to said outlet,

a controller or processor configured to energise said heater according to at least a user selectable level,

a cover configured to prevent user selection of said heating level and providing an outlet directly from said device,

15 wherein when said chamber is installed in proximity to said heater said apparatus delivers humidified gas to a patient at a predetermined pressure level,

and when said chamber is removed and said cover is installed said apparatus delivers unhumidified gas to a patient at a predetermined pressure level.

14. An apparatus as claimed in claim 13 wherein said cover may be removed using a
20 mechanical key to disengage it with said apparatus.

15. An apparatus as claimed in claim 14 further comprising a control input configured to provide user selection to said controller.

16. An apparatus as claimed in claim 15 wherein said input may be locked to prevent user input and unlocked by engaging a mechanical key with said input.

25 17. An apparatus for delivering gas to a patient comprising a gas delivery device configured to provide gas at a predetermined pressure level,

a heater,

a chamber having an inlet and an outlet,

said inlet configured to receive gas from said device,

including a body of water whereby said body of water being heated by said heater providing vapour within said chamber thereby humidifying gases passing from said inlet to said outlet,

a controller or processor configured to energise said heater according to at least a user selectable level.

a user input configured to selectively enable or disable said heater and/or other functionality associated with said apparatus.

- 10 18. An apparatus as claimed in claim 17 further comprising a display adapted to indicate the current level of functionality enabled.

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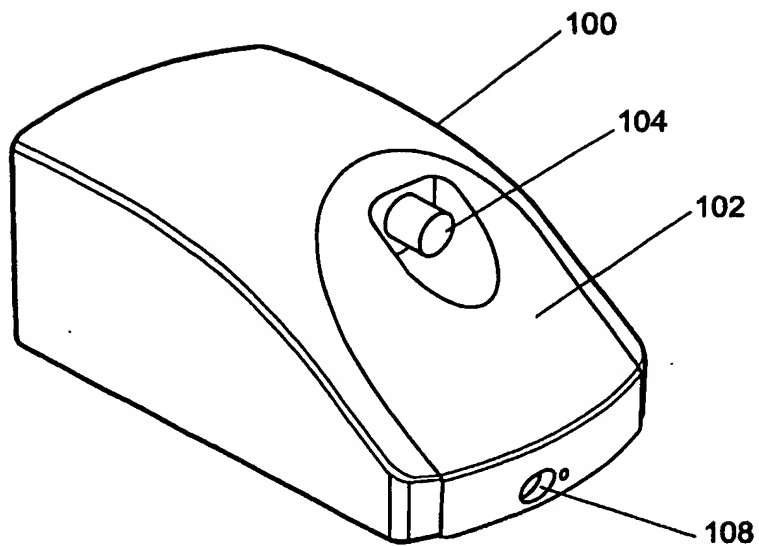


FIGURE 1

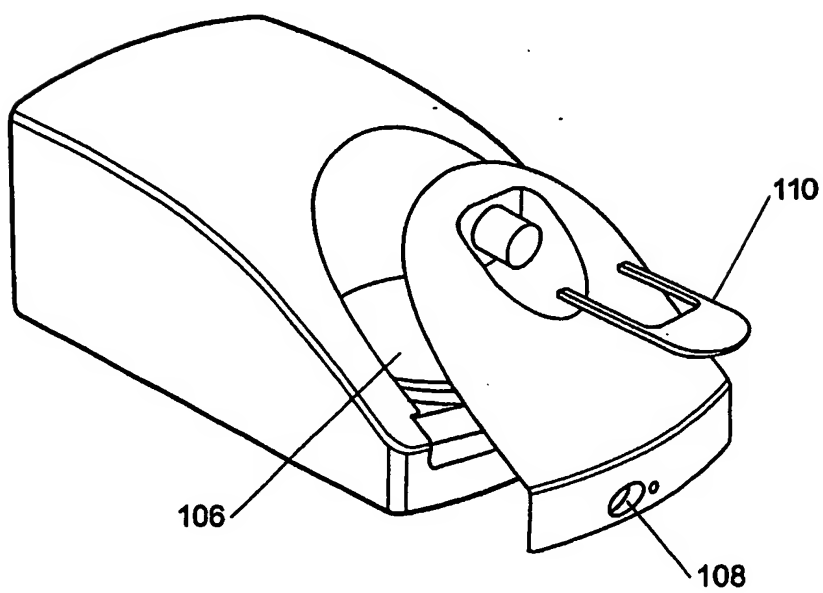


FIGURE 2A

2/3

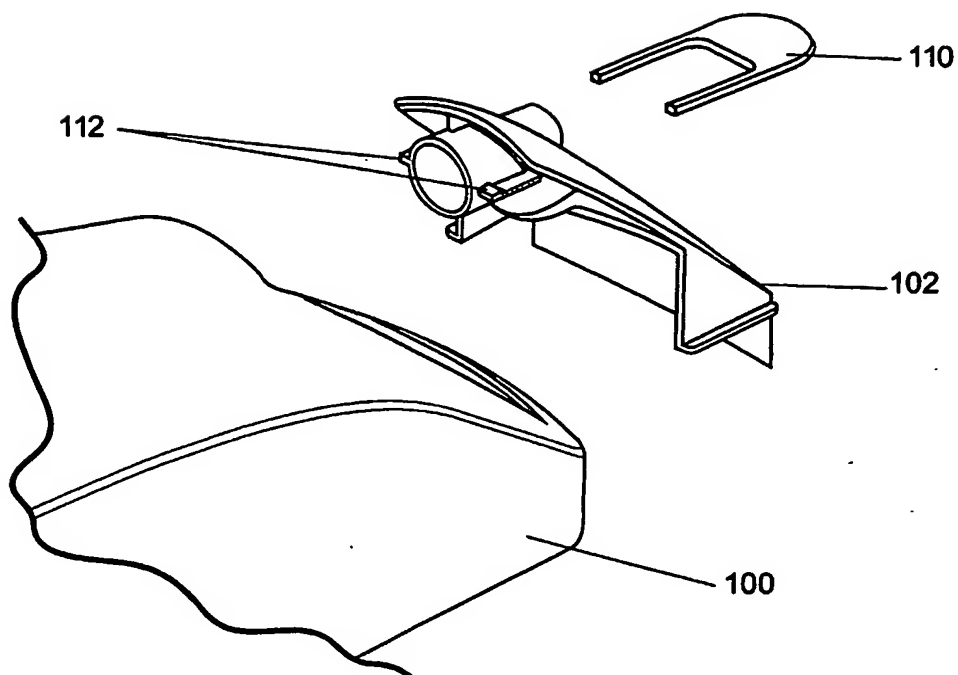


FIGURE 2B

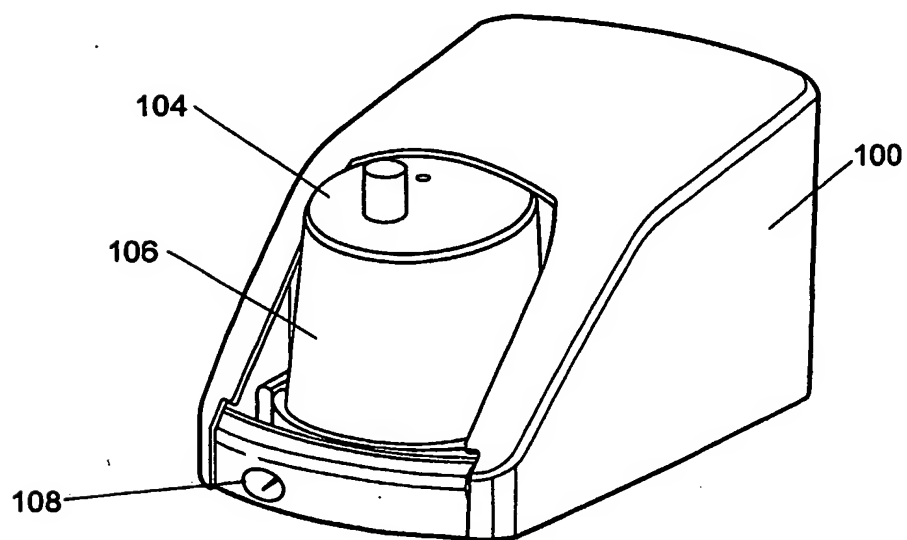


FIGURE 3

3/3

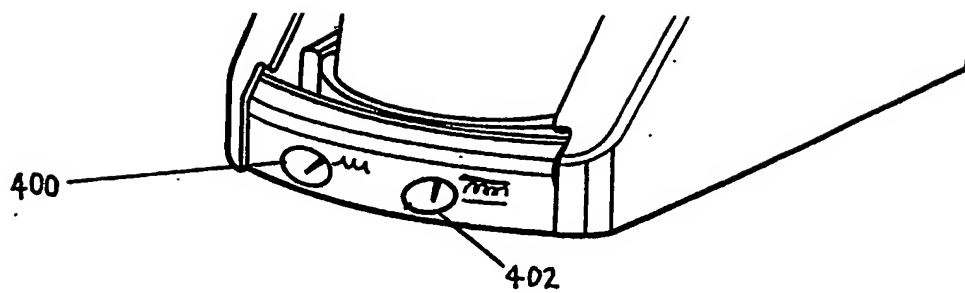


FIGURE 4

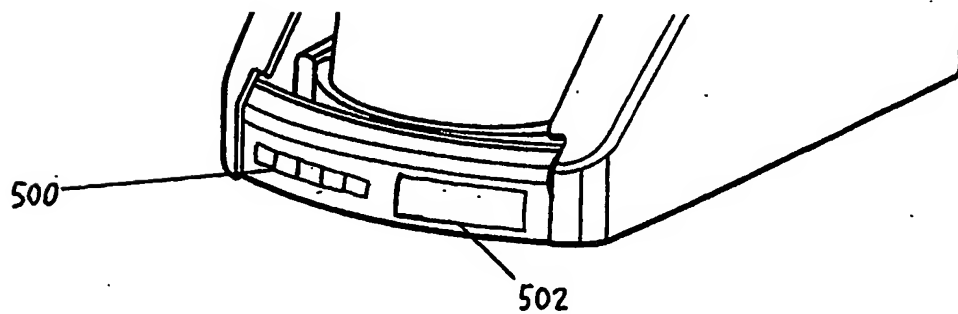


FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2003/000243

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61M 16/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

SEE ELECTRONIC DATABASES CONSULTED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI: humid, water, vapor, vapour, on, off, switch, opera, enable, disable, A61M 16/ A62B .

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 9-276408 (SANYO DENSHI KOGYO KK) 28 October 1997 Abstract, Fig.1.	1-18
X	DE 19630466 (NETZER NIKOLAUS) 5 February 1998 Abstract, Fig 1-4.	1-18
X	WO 2001/010489 A2 (MAP MEDIZINTECHNIK FUR ARTZ UND PATIENT GMBH & CO. KG) 15 February 2001 Abstract, Fig. 1-6.	1-18

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex

- * Special categories of cited documents:
- | | |
|---|--|
| "A" document defining the general state of the art which is not considered to be of particular relevance | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "E" earlier application or patent but published on or after the international filing date | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
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| "O" document referring to an oral disclosure, use, exhibition or other means | "&" document member of the same patent family |
| "P" document published prior to the international filing date but later than the priority date claimed | |


Date of the actual completion of the international search
17 February 2004

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23 FEB 2004

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2003/000243

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
JE	9276408	NO	FAMILY				
DE	19630466	AU	4202797	WO	09804311		
WO	01/10489	AU	6570600	DE	19936499	DE	19949283
		DE	19949292	DE	20022730U	DE	29918048U
		EP	1210139	JP	2003506161T	WO	0110489
END OF ANNEX							